

*B3*  
interaction in the absence of the candidate medicament as a candidate for an effective medicament.

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7. (Amended) The method according to claim 3, wherein the medicament tested is

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selected as a candidate for an effective medicament when the medicament decreases or increases the interaction of a NADE-apoptosis related protein complex.

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#### **REMARKS**

Initially, Applicants thank the Examiner for withdrawing the finality of the Office Action of record.

Reconsideration and withdrawal of the rejections of record is respectfully requested.

#### ***Summary of Status of Amendments and Office Action***

In the present amendment, claims 3-5 and 7 are amended and claims 1-2 and 6 are canceled. Therefore, claims 3-5 and 7 are pending in the application with claim 3 being independent.

Claim 5 and 6 remain rejected under 35 U.S.C. § 112, first paragraph as allegedly not enabled.

Claims 1-7 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly being indefinite.

Claim 6 remains rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter not described in the specification in such a way to convey possession to one of

ordinary skill in the art.

Claims 1 and 2 are rejected under 35 U.S.C. § 102 (b) as anticipated by Garkavtsev et al., Ichimura et al., Imataka et al., Kalchman et al., or Su et al.

***Response to §112, First Paragraph Rejections***

Claims 5 and 6 are rejected under 35 U.S.C. § 112, first paragraph as nonenabled. The Office Action asserts that claim 6 is drawn to a medicament, but the specification does not teach how to make and use a medicament. The Office Action also asserts that claim 6 as contains subject matter not described in the specification in such a way to convey possession to one of ordinary skill in the art. With respect to both claims 5 and 6, the Examiner asserts that the specification does not identify the claimed “medicaments” which have been identified by screening, nor are they described in the specification. The Examiner asserts that it would require undue experimentation to one skilled in the art to practice the invention as claimed.

In response, Applicants note that they have canceled claim 6, which is directed to medicaments obtained by the method of claim 3, without prejudice in order to allow prosecution to advance.

With respect to the rejection of claim 5, it is again respectfully submitted that the rejection is based on a misunderstanding of the claimed invention. Applicants note that the Office Action is based on the premise that Applicants are claiming compounds which would *per se* treat, prevent and/or diagnose a disease. However, the rejection does not apply because Applicants claims recite “[a] method for screening a candidate medicament for treatment and/or

prevention of an apoptosis-associated disease” the protein (claim 1, emphasis added). Thus, claim 5 recites a method of screening candidate medicaments, not the medicament to treat, prevent and/or diagnose a disease *per se*. Therefore, Applicants respectfully submit that the basis for the rejection of claim 5 does not apply to the claimed invention and should be withdrawn.

***Response to §112, Second Paragraph Rejections***

Claims 1-7 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite. The Office Action asserts that claims 1, 3 and 6 are indefinite because it is not clear how a medicament is used for diagnosis. In response, claims 1 and 6 have been canceled without prejudice, and claim 3 has been amended to delete the term “diagnosis.” Therefore, Applicants respectfully submit that the basis for the rejection of claim 3 is moot and should be withdrawn.

The Office Action also asserts that claim 3 is indefinite for use of the term “interaction.” In return, Applicants have amended the claim by deleting the term “interaction” and replacing it with “binding.” Therefore, Applicants respectfully submit that the basis for the rejection of claim 3 is moot and should be withdrawn.

The Office Action also asserts that claim 5 is indefinite because “the claim is drawn to screening of a medicament and but the active step says the screening assay is performed in presence of yet unscreened medicament.” In response, Applicants note that the claim language is entirely appropriate because there is no way to screen an unscreened compound without actually screening the compound. Therefore, Applicants respectfully submit that the rejection is should be reconsidered and withdrawn.

The Office Action asserts that claim 2 is indefinite for use of the term “Huntingtin.” In response, Applicants note that claim 2 has been canceled, and the rejection is moot.

The Office Action asserts that claims 3-6 are indefinite for omitting essential elements, including a contacting step, a detection step and a correlation step. In response, Applicants note that claim 6 has been canceled and the rejection is moot. With respect to the rejection of claims 3 and 4, Applicants note that the claimed method is a method of screening by detecting whether the candidate medicament has an effect on the binding of NADE to an apoptosis-related protein. The steps which are alleged to be missing are all inherent in the claimed method, and are unnecessary or are already inherently recited in claims 3 and 4. With respect to claim 5, Applicants have amended claim 5 to even more clearly set forth the invention and even more positively recite the method. Therefore, Applicants respectfully submit that the rejection should be withdrawn.

Finally, the Office Action asserts that claim 7 is indefinite because the metes and bounds of the term “pharmacological action of a NADE-apoptosis related complex” is unclear, and the term “the pharmacological action” lacks antecedent basis. In response, Applicants have amended claim 7 to expressly state that the pharmacological action is the interaction between NADE and an apoptosis related protein. Support for this position is found at pages 4-6 of the specification.

Applicants also wish to point out the statement in the Office Action that “[a] method for screening a medically useful candidate compound using NADE and NADE-binding proteins listed in claims 1 and 2 are novel and does not require undue experimentation.” The Office Action suggests rewriting claim 1 as a method claim, and then canceling claim 5 as redundant.

Instead, Applicants have amended claim 5 to more clearly set forth their claimed invention and to include language from claim 1, not previously found in claim 5. Applicants have added the term “candidate medicament” in place of the term “medicament.” Support for this language is found on page 9 of the specification. Applicants respectfully submit that they have essentially followed the Examiner’s suggestions, and claim 5 is “novel and does not require undue experimentation.”

Therefore, Applicants respectfully submit that the rejection of claims 3-5 and 7 under 35 U.S.C. §112, second paragraph is overcome, and should be withdrawn.

*Response to §102 (b) Rejection*

Claims 1 and 2 are rejected under 35 U.S.C. § 102 (b) as anticipated by Garkavtsev et al., Ichimura et al., Imataka et al., Kalchman et al., or Su et al. In response, Applicants have elected to cancel claims 1 and 2 without prejudice to advance prosecution of the remaining claims. Applicants action in canceling claims 1 and 2 should not be construed as Applicants’ acquiescence to the rejection and Applicants expressly reserve the right to pursue these claims in a divisional application.

**CONCLUSION**

For the reasons advanced above, Applicants respectfully submit that all pending claims patentably define Applicants' invention. Allowance of the application with an early mailing date of the Notices of Allowance and Allowability is therefore respectfully requested. If any issues remain which may be expeditiously resolved by a telephone conference, the Examiner is

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remain which may be expeditiously resolved by a telephone conference, the Examiner is respectfully invited to telephone the undersigned at the below listed number to discuss the same.

Respectfully submitted,  
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**Marked-Up Copy of the Amended Claims**

3. (Amended) A method for screening a candidate medicament for treatment[,] and/or prevention [and/or diagnosis] of an apoptosis-associated disease which comprises the step of detecting [interaction] binding between NADE (p75NTR-associated cell death executor) and an apoptosis related protein which binds to NADE in the presence of a candidate medicament to be tested.

4. (Twice Amended) The method according to claim 3, wherein the candidate medicament tested is selected as a candidate of an effective medicament when the candidate medicament inhibits or increases the interaction between NADE and an apoptosis related protein which binds to NADE.

5. (Amended) The method according to claim 3, which comprises [the steps of]

(a) [subjecting] allowing NADE and [the] an apoptosis related protein which binds to NADE to interact with each other in the presence of the candidate medicament to be tested,

(b) [subjecting] allowing NADE and [the] an apoptosis related protein which binds to NADE to [interaction] interact with each other in the absence of the candidate medicament to be tested,

(c) detecting the interactions in [the steps] (a) and (b), and

(d) comparing the interactions in [the steps] (a) and (b)

(e) [to choose] choosing the candidate medicament having an effect on the interaction when compared to the interaction in the absence of the candidate medicament as a candidate [of] for an effective medicament.

7. (Amended) The method according to claim 3, wherein the medicament tested is

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selected as a candidate [of] for an effective medicament when the medicament decreases or increases the [pharmacological action] interaction of a NADE-apoptosis related protein complex.